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California Pedigree Law

GS1 Global Meeting
April 2013

California Pedigree Regulation

- **What Is California ePedigree**

- **California Pedigree Law Requirements**

- **Key Implementation Dates**

- **Industry Working With BOP**

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What is California ePedigree?

- **California Pedigree Definition**
  - A record, in <u>electronic form</u>, containing information regarding each transaction resulting in a <u>change of ownership</u> of a given dangerous drug, from sale by a manufacturer, through acquisition(s) and sale(s) by one or more wholesalers, manufacturers, or pharmacies, until final sale to pharmacy or other person furnishing, administering or dispensing the dangerous drug.

California Pedigree Law Requirements

- **A Pedigree tracks each prescription drug at the <u>smallest package or immediate container</u> distributed by the manufacturer, received and distributed by the wholesaler and received by the pharmacy.**

- **Pedigree shall be created and maintained in an <u>interoperable</u> electronic system, ensuring compatibility throughout all stages of distribution**
  - **An approved ePedigree format is the GS1 Drug Pedigree Messaging Standard (DPMS)**

  - **GS1 Working Group is working to develop an EPCIS Traceability Standard to present to the BOP**

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Key Implementation Dates

- January 1, 2015 – 50% of a manufacturer's products must be serialized and pedigree's issued

- January 1, 2016 – 100% of a manufacturer's products must be serialized and pedigree's issued

- July 1, 2016 - All wholesalers and re-packagers must ensure that the products they receive are serialized and are received with a pedigree

- July 1, 2017 - Pharmacy and pharmacy warehouses, including hospitals, clinics, and retail, must ensure that the products they receive are serialized and are received with a pedigree

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Industry Working With BOP

- **California Board of Pharmacy is holding stakeholder meetings asking for input from industry on the implementation of the law**

- **California Board of Pharmacy is specifically not regulating on how industry is to exchange data. The BOP understands and supports our choice of GS1 Standards.**

- **Manufacturers and wholesalers are engaged in pilots to test both serialization and the exchange of electronic data to provide feedback to BOP**

Industry Challenges

- **Manufacturer aggregation**
- **Use of Inference**
- **'Certification' of the data by participants**
- **Grandfathering of un-serialized / non-pedigreed product**
- **Digital signatures**
- **Re-packaged product pedigrees**